



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

JS

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/056,806 04/08/98 VERMEULEN

A I/97272

EXAMINER

HZ12/0905

WILLIAM M BLACKSTONE
AKZO NOBEL
1300 PICCARD DRIVE NO 206
ROCKVILLE MD 20850-4373

TURNER, S	
ART UNIT	PAPER NUMBER

1647
DATE MAILED:

16
09/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/056,806

Applicant(s)

Vermeulen

Examiner
Sharon L. Turner, Ph.D.

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6-28-01
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 18, 19, and 21-32 is/are pending in the application.
- 4a) Of the above, claim(s) 6-11, 18, 21-26, 29, and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12-15, 19, 27, 28, 30, and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-15, 18, 19, and 21-32 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

Art Unit: 1647

Continued Prosecution Application

1. The request filed on 6-28-01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/056,806 is acceptable and a CPA has been established. An action on the CPA follows.
2. The amendment filed 5-21-01 has been entered into the record and has been fully considered. Claims 1-15, 18-19, and 21-32 are pending.
3. Claims 6-11, 18, 21-26, 29 and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.
4. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

Specification

5. The amendment filed 9-27-99 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: As previously set forth the new insertion at p. 19, line 19 inserting (a saponin) in reference to Quil A serves to broaden support from that which was initially contemplated by the specification. It is noted that this rejection was previously presented as to claims 14 and 28 which recitations in the claims have been corrected. However, the new matter has not been removed from the specification.

Art Unit: 1647

In particular, the specification has been amended from "Quil A" to recite "a saponin." The amendment is deemed to introduce new matter into the specification because there does not appear to be written description support for the broad genus of saponins encompassed by the claims. In particular, the examiner notes that a search of the registry file indicates 1130 saponins known in the literature as exemplified by for example by assamsaponin H, G and F, see in particular registry numbers 316157-17-2, 316157-16-1 and 316157-15-0, whereas a search of the registry file indicates Quil-A limited to registry numbers 227621-56-9, 227621-94-5 and 66594-14-7, exemplified by Sorbitan, tri-(9z)-9-octadecenoate, mixt. with (3.beta.)-cholest-5-en-3-ol, (6E, 10E, 14E, 18E)-2,6,10,15,19,23-hexamethyl-2,6,10,14,18,22-tetracosahexaene, Quil-A and sorbitan mono-(9Z)-octadecenoate poly (oxy-1,2-ethanediyl)derivatives (9CI). Thus, the genus of molecules represented by saponins appears to be broader in scope than the species of Quil A saponins supported by the specification at for example p. 19, line 18 as pointed to by applicants. Thus, the broad recitation of "a saponin" appears to introduce new matter.

Applicant is required to cancel the new matter in the reply to this Office action.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5, 12-15, 19, 27, 28, 30 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

Art Unit: 1647

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants point to support for claim 1 amendments at p. 4, lines 1-5.

The examiner notes that p. 4, lines 1-5 state:

“A composition of the present invention will normally be free of one or more Eimeria proteins which occur in Eimeria in nature. Preferably it will be substantially free of Eimeria proteins, other than Eimeria proteins which are present in the hydrophilic phase of a Triton X-114 detergent extract of Eimeria sporozoites. Proteins which are membrane-bound in Eimeria may therefore be absent.”

However, claim 1 as amended recites “wherein said composition is substantially free of proteins which are membrane-bound in Eimeria”. In particular, the claim and specification appear to differ in scope as the specification implies that the proteins present in the hydrophilic phase are included and that thus some membrane-bound proteins may be absent. However, in contrast the claim appears to imply that the preparation has been removed of substantially all membrane-bound proteins. Thus, the new limitation appears to impart a difference in scope as implied by a step not specifically recited and thus appears to be a limitation not supported by the specification as filed. It is noted that for the purposes of prior art the limitation does not appear to further limit the composition.

8. Claims 1-5, 12-15, 19, 27, 28, 30 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “substantially free of proteins which are membrane bound,” yet it is unclear to the skilled artisan how such limitation further defines the composition from that

Art Unit: 1647

previously recited in the claim, i.e., that the proteins present are those in the hydrophilic phase of the extract. Applicants should clarify whether the limitation is intended to further define or limit the protein composition by the implication of a further purification step from that of the hydrophilic phase previously recited in the claim. For the purposes of prior art, the new limitation does not appear to further limit the protein composition.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-5, 12-15, 19, 27, 28, 30 and 32 stand rejected as previously set forth in Paper Nos 5, 9 and as reiterated herein under 35 U.S.C. 102(b) as being anticipated by EP0382531, Gurnett, 16.08.90.

Applicants argue that the newly amended claim 1 is not taught or suggested by Gurnett. In particular the examiner notes that the new limitation of claim 1 is that “the composition is substantially free of proteins which are membrane-bound in Eimeria.” The Gurnett teachings are noted as set forth. Applicants argue that the Gurnett teachings fail to teach the composition of claim 1 as amended in that the composition is required to be substantially free of proteins which are membrane bound. Applicants suggests that it is the hydrophobic proteins which are

Art Unit: 1647

membrane bound as taught by Gurnett which are the proteins relied on by the examiner for the prior art rejection and that thus the rejection should be withdrawn.

Applicant's arguments filed 5-21-01 have been fully considered but are not persuasive. Applicants appear to be of the position that because lipase is required for some of the noted membrane bound proteins to partition to the hydrophilic phase that the limitation "substantially free of membrane-bound proteins" removes the Gurnett preparation from applicable prior art. The Gurnett reference teaches preparations processed with and without lipase. However, the reference cannot be distinguished from the claims because the Gurnett reference teaches that when the lysates are treated after phase separation the hydrophobic glycolipid linked proteins are found in the detergent phase. However, when lipase is added prior to phase separation, the proteins are found in the aqueous (hydrophilic) phase, see in particular Example 5, p. 9, lines 52-53 and Example 6, p. 10, lines 24-27. The reasoning that the reference should be removed is completely unclear to the examiner firstly because the limitation is not free of membrane-bound proteins as argued but "substantially free" as recited, which metes and bounds cannot be discerned by the artisan. Secondly, regardless of the limitation Gurnett still teaches both preparations, either with or without lipase cleavage of membrane bound proteins and thus the preparations of Gurnett are not distinguished from that claimed by Applicant because the preparations are not distinguished from the peptide preparations of the prior art as to the constituent proteins. It is noted that the molecular weight determination of the four major glycolipid linked proteins from *E. tenella* sporozoites prepared via such methods as demonstrated

Art Unit: 1647

in Examples 5 and 6 (see also Table II) reveal that the proteins which may be isolated either in the hydrophilic fraction (when lipase is added prior to phase separation) or the hydrophobic fraction (when lipase is added after phase separation) exhibit the desired molecular weight characteristics of applicants claims. As the evidence shows that the disclosed proteins may be isolated from either the hydrophilic phase of a triton X-114 detergent extraction, or the hydrophobic phase of a triton X-114 detergent extraction, the disclosed peptide compositions of Gurnett cannot be distinguished from the compositions and vaccines claimed and thus the claims are inherently anticipated by the prior art based on the similar compositional preparations. Applicants are reminded that the Gurnett reference teaches the vaccine compositions for vaccination with carriers, and with adjuvant, see in particular p. 3, line 40, p. 5, lines 46-48 and p. 7, lines 27-45. For immobilization or labeled compositions, see in particular Examples 1-12.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

Art Unit: 1647

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 14 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP0382531, Gurnett et al., 16.08.90, MacKenzie et al., US4,981,684, Jan. 1, 1991 and Estrada et al., US 5,597,807, Jan. 28, 1997.

Gurnett et al., is set forth above and teaches the composition of claim 1 and vaccine compositions with carrier and adjuvant.

Gurnett et al., fail to teach the composition wherein the adjuvant is Quil A.

MacKenzie et al., teach as of 1991 the knowledge of one of skill in the art who recognized the use of adjuvant complexes, specifically where the glycoside is Quil A (Quillaja saponin) for use in the formulation of vaccines suitable for immunization against pathogens including Eimeria, see in particular Abstract, column 2, lines 43-44 and column 3, line 47.

Estrada et al., similarly teach that as of 1-28-97 (prior to applicants invention) that Quillaja saponins, (Quil A) are especially advantageous to the promotion and production of isoform specific immunoglobulin, specifically IgG and IgA antibodies which enhance both humoral and secretory immune responses in invertebrates, see in particular columns 5-6, General Methods. Estrada also particularly points to the use of Quillaja saponins in Eimeria vaccine preparations, see in particular column 6, line 30.

Art Unit: 1647

Thus, it would have been prima facie obvious to one of skill in the art at the time of invention to modify the vaccine of Gurnett et al., using the adjuvant Quil A to provide for the advantageous and superior benefits of stimulating IgG and IgA antibodies against the Eimeria antigens for the purpose of producing protective immunity in mammalian hosts. The skilled artisan would have motivation to do so and would have expected positive results given the teachings of Gurnett, MacKenzie and Estrada as set forth above and as exemplified in the various references. Thus, the cumulative reference teachings render the claimed invention obvious to the skilled artisan.

Status of Claims

13. No claims are allowed.

Conclusion

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
September 4, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud